According to Be the Match, more than 40,000 patients have received cord blood transplants.

The reauthorization before us authorizes $23 million each year for 5 years for the cord blood side and, again, some $30 million each year for the bone marrow program.

Mr. Speaker, each year, nearly 4 million babies are born in America. In the past, virtually every placenta and umbilical cord was tossed as medical waste. Today, doctors have turned this medical waste into medical miracles.

Not only has God, in His wisdom and goodness, created a placenta and an umbilical cord to nurture and protect the precious life of an unborn child, but now we know that another gift awaits immediately after birth. Something very special is left behind: Cord blood that is teeming with lifesaving stem cells.

Mr. BILIRAKIS. Mr. Speaker, this is a very important bill and needs to pass as soon as possible. I really appreciate the chairman placing the bill on the agenda. I urge the Senate to pass it as soon as possible, and, of course, my colleagues today, if we can pass this bill immediately so we can get it to the Senate.

Mr. Speaker, I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I also urge support for the bill, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 941.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. CLINE. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

ADVANCING EDUCATION ON BIOSIMILARS ACT OF 2021

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (S. 164) to educate health care providers and the public on biosimilar biological products, and for other purposes.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 164

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Advancing Education on Biosimilars Act of 2021''.

SEC. 2. EDUCATION ON BIOLOGICAL PRODUCTS.

Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by adding at the end the following:

''SEC. 352A. EDUCATION ON BIOLOGICAL PRODUCTS.

''(a) INTERNET WEBSITE.—

''(1) IN GENERAL.—The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

''(2) CONTENT.—Educational materials provided under paragraph (1) may include—

''(A) explanations of key statutory and regulatory terms, including 'biosimilar' and 'interchangeable', and clarification regarding the use of interchangeable biosimilar biological products;

''(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

''(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

''(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 351(k) and reference products (as defined in section 351(i)), including the standards for review and licensing of each such type of biological product.

''(3) FORMAT.—The educational materials provided under paragraph (1) may be—

''(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

''(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

''(4) OTHER INFORMATION.—In addition to the information described in paragraph (2), the Secretary shall continue to publish—

''(A) the action package of each biological product licensed under subsection (a) or (k) of section 351; or

''(B) the summary review of each biological product licensed under subsection (a) or (k) of section 351.

''(5) CONFIDENTIAL AND TRADE SECRET INFORMATION.—This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

''(b) CONTINUING EDUCATION.—The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Florida (Mr. BILIRAKIS) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and include extraneous material on S. 164.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, the rising cost of prescription drugs continues to be a major issue for families all across the country. These costs are particularly daunting at a time when we are facing a severe economic downturn and the ongoing pandemic.

We are committed to continuing to find solutions to make prescription drugs more affordable for the American people. One important way to help families out is to ensure they are aware of more affordable options, like biosimilars and generics. These are both cheaper options, but, unfortunately, utilization of these products continues to be too low here in the United States.

The Advancing Education on Biosimilars Act of 2021 is commonsense legislation that will help provide patients and healthcare providers with greater information about biologics and biosimilars. To do this, the bill requires the FDA to establish a public website with educational materials, including what products are interchangeable, as well as how to report any adverse events.

In addition, the bill would support the development of continuing education programs for healthcare providers about biologics. It is critical that healthcare providers and patients are aware of all of their options, and this legislation will certainly help do that.

I am pleased to work with my colleagues in the Senate on this legislation, and I urge my colleagues to support the bill.

Mr. Speaker, I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of S. 164, the Advancing Education on Biosimilars Act.

This bill is a bipartisan companion to H.R. 1873, championed in the House by Dr. BUCSHON and Congressman PETERS.

This bill would require the FDA to maintain and operate an internet website to provide educational materials for healthcare providers, patients, and caregivers on biological products, including biosimilar products and interchangeable biosimilar products.

It also would require the Department of Health and Human Services, HHS, to develop continuing education programs or to improve existing programs for healthcare providers, such as doctors and nurses, to promote a better understanding of biosimilar interchangeable products.

By increasing awareness about available biosimilar products and providing educational resources for physicians

and patients about their benefits, we can increase adoption of these lower cost alternative therapies when appropriate and drive down drug costs for Americans across the country.

Mr. Speaker, I urge support for this bipartisan effort to lower drug costs through the uptake of biosimilar products, and I reserve the balance of my time.

□ 1315

Mr. PALLONE. Mr. Speaker, I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as he may consume to the gentleman from Indiana (Mr. BUCSHON), a great member of the Energy and Commerce Committee and a great resource for us nonphysicians.

Mr. BUCSHON. Mr. Speaker, I would like to speak in support of S. 164, the Advancing Education on Biosimilars Act of 2021, which is the Senate companion of H.R. 1873, a bill that I introduced with my friend and colleague, Congressman SCOTT PETERS from California.

This bipartisan, bicameral bill will require FDA to create a public website to educate patients and providers about biological and biosimilar products.

As new biological and biosimilar products become available, it is important that physicians have current information on these therapies in order to choose the best treatment for their patients.

Availability of information and education on these new and complex treatments for providers and patients will lead to healthy competition in the biologic and biosimilar product space and ultimately help to lower the cost of these important drugs for patients.

I urge my colleagues to support this bill, and I look forward to the President signing it into law.

Mr. PALLONE. Mr. Speaker, I have no additional speakers.

Mr. BILIRAKIS. Mr. Speaker, I urge everyone to vote to pass this bill so we can quickly make this law and get it to the President.

Mr. Speaker, I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I also urge support for this bill, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, S. 164.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. CLINE. Mr. Speaker, on that I demand the yeas and nays.

The SPEAKER pro tempore. Pursuant to section 3(s) of House Resolution 8, the yeas and nays are ordered.

Pursuant to clause 8 of rule XX, further proceedings on this motion are postponed.

AMENDING FEDERAL FOOD, DRUG, AND COSMETIC ACT WITH RESPECT TO SCOPE OF NEW CHEMICAL EXCLUSIVITY

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (S. 415) to amend the Federal Food, Drug, and Cosmetic Act with respect to the scope of new chemical exclusivity.

The Clerk read the title of the bill.

The text of the bill is as follows:

S. 415

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. CLARIFYING THE MEANING OF NEW CHEMICAL ENTITY.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(B) in subsection (j)(5)(F), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(C) in subsection (l)(2)(A)—

(i) by amending clause (i) to read as follows:

''(i) not later than 30 days after the date of approval of such applications—

''(I) for a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(II) for a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; and''; and

(ii) in clause (ii), by inserting ''or biological product'' before the period;

(D) by amending subsection (s) to read as follows:

''(s) REFERRAL TO ADVISORY COMMITTEE.—The Secretary shall—

''(1) refer a drug or biological product to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee prior to the approval of such drug or biological if it is—

''(A) a drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under this section; or

''(B) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act; or

''(2) if the Secretary does not refer a drug or biological product described in paragraph (1) to a Food and Drug Administration advisory committee prior to such approval, provide in the action letter on the application for the drug or biological product a summary of the reasons why the Secretary did not refer the drug or biological product to an advisory committee prior to approval.''; and

(E) in subsection (u)(1), in the matter preceding subparagraph (A)—

(i) by striking ''active ingredient (including any ester or salt of the active ingredient)'' and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))''; and

(ii) by striking ''same active ingredient'' and inserting ''same active moiety'';

(2) in section 512(c)(2)(F) (21 U.S.C. 360b(c)(2)(F)), by striking ''active ingredient (including any ester or salt of the active ingredient)'' each place it appears and inserting ''active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations))'';

(3) in section 524(a)(4) (21 U.S.C. 360n(a)(4)), by amending subparagraph (C) to read as follows:

''(C) is for—

''(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

''(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.'';

(4) in section 529(a)(4) (21 U.S.C. 360ff(a)(4)), by striking subparagraphs (A) and (B) and inserting the following:

''(A) is for a drug or biological product that is for the prevention or treatment of a rare pediatric disease;

''(B)(i) is for such a drug—

''(I) that contains no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) that has been previously approved in any other application under subsection (b)(1), (b)(2), or (j) of section 505; and

''(II) that is the subject of an application submitted under section 505(b)(1); or

''(ii) is for such a biological product—

''(I) that contains no active ingredient that has been previously approved in any other application under section 351(a) or 351(k) of the Public Health Service Act; and

''(II) that is the subject of an application submitted under section 351(a) of the Public Health Service Act;''; and

(5) in section 565A(a)(4) (21 U.S.C. 360bbb–4a(a)(4)), by amending subparagraph (D) to read as follows:

''(D) is for—

''(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 505(b)(1); or

''(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act.''.

(b) TECHNICAL CORRECTIONS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended—

(1) in section 505 (21 U.S.C. 355)—

(A) in subsection (c)(3)(E), by repealing clause (i); and

(B) in subsection (j)(5)(F), by repealing clause (i); and

(2) in section 505A(c)(1)(A)(i)(II) (21 U.S.C. 355a(c)(1)(A)(i)(II)), by striking ''(c)(3)(D)'' and inserting ''(c)(3)(E)''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Florida (Mr. BILIRAKIS) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to